Laboratory Registration/Select Agent Transfer Program
Application for Laboratory Registration

This application package is for facilities required to register to transfer or receive select agents under Public Law 104-132 and its implementing regulation (42 CFR 72.6 - *Additional Requirements for Facilities Transferring or Receiving Select Agents*).

Oversight of facility registration and tracking of select agent transfers required by the regulation has been delegated by the Department of Health and Human Services to the Centers for Disease Control and Prevention (CDC).

The law and regulation require that a responsible facility official be identified, that the facility demonstrate its ability to work safely with select agent(s), and that registered facilities keep records of select agents transferred to and from their facilities.

All facilities required to register must complete the portions of the application package that are applicable to the select agents with which they intend to work, and must submit the completed application package with the required site registration fee to CDC. The application will then be reviewed by CDC. If information supplied in the application package indicates that the facility is properly equipped to handle and transfer select agents, CDC will issue a registration number to the facility. The registration is valid for three years. All facilities will be inspected at least once during the three year registration period. If a facility's application fails to document that the facility is properly equipped to work with select agents, or if the application is incomplete, the facility will not be registered. CDC will inform the facility of the problems with the facility and/or the application. When these problems are resolved by the facility, the facility may again seek registration.

Contents of this application package:

Forms to be completed by applicants. Some of these must be completed by all applicants, some are specific to a group of select agents (e.g., toxins), and must be completed only by facilities working with those agents:

1) ***Background Information/Certification and Signature*** form - to be completed by all facilities required to register under 42 CFR 72.6. This form must be signed by the responsible safety official for your institution.

2) ***Information on Select Agents*** - a set of forms requesting more detailed information on the select agents you intend to transfer or receive and the laboratories you plan to use for work with those select agents. Because the facilities, equipment and procedures of laboratories working with bacteria, viruses, fungi or rickettsiae, recombinant DNA, and toxins may be different, there is a different form for each group of select agents. You will be asked to complete the form or forms describing the type of work you do and the laboratories you use for the select agents that you transfer or receive at your institution.

3) ***Laboratory Assessment Instruments*** - a set of self-evaluation instruments based on the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) (for the bacteria viruses, fungi and rickettsiae), the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines) (for recombinant DNA work) and 29 CFR 1910.1450 (for laboratories working with select agent toxins). A facility will complete only the laboratory assessment instruments required for the type(s) of select agent(s) with which that facility intends to work.

Laboratories working with live select agent bacteria, viruses, fungi or ricketts iae will complete the appropriate BMBL-based assessments.

Laboratories working with recombinant DNA may complete either the appropriate BMBL-based assessments, or those based on the *NIH Guidelines*. The responsible facility official may determine which assessment instruments are to be used, based on which document is used for that institution's policies and procedures for work with those select agents. Institutions using recombinant DNA for large animal studies or in large scale production are asked to complete those assessments based on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.

Laboratories working with select agent toxins must meet additional specific requirements of 29 CFR 1910.1450. These laboratories must complete the 29 CFR based assessment instrument. Laboratories working with select agent toxins must also complete the laboratory assessments based on the BMBL and/or *NIH Guidelines*, if the toxin work involves working with recombinant DNA or intact toxin producing organisms.

Attachments: Attachments include the regulation and several update/clarification documents. All applicants should review these before starting to work with the application forms.

1) 42 CFR 72.6 .

2) Federal Register Notice - *Notice of Site Registration Fee Schedule...*. This document contains the user fee schedule and several corrections/clarifications to the regulation.

3) Table of Select Agent Toxins - LD_{50} for Mice.

4) Federal Register Notice - *Suspension of Site Registration Fee for Facilities Transferring or Receiving Select Agents*. This document announces the suspension of the site registration fee, effective November 27, 1998.

5) A summary of the recommended biosafety levels for several recently identified viruses that are not included in the current edition of the BMBL.

Additional materials you will need:

1) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 3rd ed - if you will be transferring or receiving any of the select agent bacteria, viruses, ricketts iae or fungi.

2) *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines),* March 1996 or more recent edition - if you will be transferring or receiving genetically modified organisms or genetic elements from the list of select agents that produce or encode for a factor associated with disease, or that contain nucleic acid sequences coding for toxins included in the select agent list, and if you use the *NIH Guidelines* as the basis for biosafety related policies and procedures in your facility.

3) 29 CFR 1910.1450 - *Occupational Exposure to Hazardous Chemicals in the Laboratory* - if you will be transferring or receiving any of the toxins on the select agent list.

4) Additional information and clarification is available through the CDC Laboratory Registration/Select Agent Transfer Program website: www.cdc.gov/od/ohs/lrsat.htm.

How to obtain the BMBL, *NIH Guidelines*, and 29 CFR 1910.1450:

BMBL - You may obtain a single copy of this document by faxing a request to CDC, Office of Health and Safety. The fax number is 404-639-3236.

NIH Guidelines - Available on the Internet at http://www.nih.gov/od/orda, or contact NIH (phone 301 496 9838).

29 CFR 1910.1450 - Available on the Internet at http://www.osha.gov/ or from the U.S. Government Printing Office (phone 202 512 1800).

Obtaining extra copies of the forms in this package:

One copy of each form is included in this packet. If you will be working with several select agents and/or using several laboratories, you will need additional copies of the forms. Please photocopy the originals contained in this application package to obtain the additional copies.

How the information in this application package will be used:

Each section of the application package is designed to obtain certain information required under 42 CFR 72.6.

The ***Background Information/Certification and Signature*** form will provide us with the information required under 42 CFR 72.6(c)(2)(i).

The ***Information on Select Agents*** and ***Laboratory Assessment Instruments*** will accomplish two things:

It will help you determine whether your laboratory is equipped to work safely with the select agent(s) in question, so you can take appropriate action if necessary before you apply for registration under this regulation.

. We will use the information you provide on the information sheet and laboratory assessment instruments to determine whether your laboratory meets the requirements of 42 CFR 72.6(a)(2)(ii).

The information you provide on this application will not routinely be shared with other government agencies or other entities. However, information will be provided on request to federal law enforcement agencies, and to other entities as required under the Freedom of Information Act (5 USC 552).

Who should complete this application package:

The responsible facility official must review and sign the ***Background Information/Certification and Signature*** portion of the application, and will be the person contacted if we have questions about the application. He/she should consult with others (e.g., engineering support services, scientists) as necessary to obtain the required information.

42 CFR 72.6 (j) specifies that a "responsible facility official" is the person responsible for all activities related to the handling or transfer of select agents under the regulation. For purposes of this regulation, the "responsible facility official" means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor and/or requesters facility. This person should be either a safety

officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility."

Public Reporting Burden:

Public reporting burden of this collection of information is estimated to average 120 minutes for completion of the **Background Information/Certification and Signature, Information on Select Agent Viruses, Bacteria, Rickettsiae and Fungi, and/or Information on Select Agents Containing Recombinant DNA, and/or Information on Select Agent Toxins,** forms, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed and reviewing the collection of information. The time required for completion of each **Laboratory Assessment Instrument** is estimated to average 30 minutes; with the total time required dependent on the number and types of Select Agents for which the laboratory is applying for registration. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0199)

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Forms approved
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